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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,213	02/04/2005	Jerome Besse	P69868US0	2581

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,213	BESSE ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/15/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the preliminary amendments filed on 07/30/04. Accordingly claims 1-22 and 24-27 are pending and under examination.

Claim Objections

Claims 1-22 and 24-26 are objected to for failing to start the claims with an appropriate article such as "A" or "The".

Claims 6 and 24 are objected to because of the following informalities:

1) The use of plus sign (+) to indicate combination of drugs is objected to.

2) Capitalizing chemical names (active agents) is objected to.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the **first paragraph** of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain mineral salts as active agents, does not reasonably provide enablement for ALL mineral salts (or inorganic salts). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. It is known in the art that some

inorganic (or mineral) salts are not therapeutic and some are even poisonous, such as lead chloride, mercury salts, uranium salts, etc.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "inorganic salt" in claim 7 does not have adequate support in the specification. Specification discloses the term "mineral salt" and not "inorganic salt". Although mineral salt and inorganic salt overlap in scope, they are not interchangeable.

The following is a quotation of the **second paragraph** of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 7, 9, 13, 22, 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 24 contain various parenthetical entries which render the claims indefinite because it is unclear whether the limitations within the entries are part of the claimed invention, whether such entries are used to describe an enantiomer of an active substance or the condition that the active agents are intended to treat, see MPEP § 2173.05.

Claims 9, 13 and 24 are indefinite for containing the term "derivative". The said derivatives have not been disclosed in the specification and their scope is

not generally known in the art. For example it is unclear what "a starch derivative" encompasses.

Claim 9 is indefinite for comprising the term "a dextrose excipient". It is not clear whether the term dextrose excipient includes other excipients (combination of dextrose and excipients) or whether it means dextrose is used as an excipient.

Claim 13 is indefinite for containing the term "a component of an essential oil". It would not be apparent to one of ordinary skill in the art what part or component of an essential oil is included in the formulation.

Claim 22 is indefinite for failing to state the claimed limitation. The statement "known to those skilled in the art" is not a specific limitation and thus the scope of the claim is unknown.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-6, 8-10, 12-18 and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Geyer et al (5,320,848).

Geyer et al teach a non-aqueous, chewable composition for **oral** delivery of unpalatable drugs. The composition contains a drug intimately dispersed or

dissolved in a pharmaceutically-acceptable lipid that is solid at room temperatures. The composition also has a matrix that contains a granulating agent for the total composition and a **rapid dispersal agent** and optionally additives such as buffering agents, flavoring agents, surfactants, and the like. Methods for the preparation of the chewable compositions are also provided (see abstract).

Geyer et al teach that chewable products can be in the form of compressed tableted material, or in the form of an un-compressed tableted material, or in the form of an uncompressed **powder**. The chewable composition preferably contains a rapid dispersal agent that is a cellulose derivative, more preferably the dispersal agent is croscarmellose sodium. The chewable composition is formulated to disperse and disintegrated rapidly in the mouth while masking the taste of the drug throughout the mastication process (Co. 2, lines 24-36). Active agents include ibuprofen, aspirin, cimetidine, acetaminophen, erythromycin, or the like (col. 2, lines 5-10). A drug-lipid mixture may be reduced to a powder and blended with a finely ground granulating agent for the drug and lipid to form a dry **powder** (col. 3, lines 29-33). The particle size can be altered, and generally the particle size is from about **10-150 microns** (col. 4, lines 12-17).

The formulations may comprise a granulating agent such as sorbitol, mannitol, dextrose, sucrose, lactose, starches or mixtures thereof (col. 4, lines 57-63). One preferred additive is a buffering agent for the drug such as sodium bicarbonate, sodium phosphates, or the corresponding calcium salts or the like (col. 5, lines 3-7). Other optional additives include sweeteners, coloring agents

and flavoring agents (col. 5, lines 15-25). Rapid dispersal agents such as starches, cellulose or its derivatives or a mixture thereof may be added (col. 5, lines 29-32). Other optional additives include phospholipids, lecithin, oils, methylcellulose, etc (col. 5, lines 59-67). Examples 1-8 also disclose formulations and their method of making.

Claims 1-3, 5, 7, 9-13, 18-19 and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Stamm et al (6,074,670).

Stamm et al teach an **immediate-release** fenofibrate composition comprising a hydrophilic polymer and optionally a surfactant, and a method for preparing it (see abstract). The said active ingredient is in a micronized form having a size **less than 20 micron** (col. 1, lines 13-20). The composition may comprise polymers such as polyvinylpyrrolidone, poly-vinyl alcohol, hydroxyl-propylmethyl cellulose, gelatin, etc (see col. 4, lines 14-26). The formulation may comprise other agents such as surfactants, wetting agents, lubricants, fillers, etc. The said optional agents include sodium lauryl sulfate, polyoxyethylene sorbitan, polyoxyethylene fatty acid glycerides, lactose, starch, colloidal silica, magnesium stearate, lecithin, etc (col. 4, lines 27-52).

Stamm et al disclose that the surfactant may be **comicronized** with fenofibrate (col. 4, lines 38-39) or the active agent is **micronized** with a polymer (col. 5, lines 58-60). The process produces granules which may be compressed

to forma tablet (col. 6, lines 12-15). Example 1 discloses a micronized fenofibrate that has a particle size of about 5 microns.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4, 7, 11 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al (EP 0839526 A2) in view of Geyer et al (5,320,848).

Ohno et al teach a solid pharmaceutical preparation comprising a pharmaceutically active ingredient, erythritol, crystalline cellulose and a disintegrant, which exhibits a fast buccal disintegration or dissolution (see abstract).

The said active agent may be in any form such as powder or granule. It is also disclosed that there is no limitation to the pharmaceutically active ingredients to be used. Many examples are listed on pages 3-4, including NSAIDs, vitamins, minerals, etc.

Ohno et al also discloses that said formulations may comprise other additives in addition to the erythritol and cellulose. The said additives include mannitol, citric acid, malic acid, aspartame, magnesium stearate, polyethylene glycol, talc, colorants, etc. The dissolution time for the said formulation is usually from about 0.1 to 1.0 minutes (page 5). Ohno et al lacks disclosure on the particle size.

Geyer et al, discussed above teaches a fast release formulation where the optimum particle size is from 10 to 150 micron.

It would have been obvious to one of ordinary skill in the art to have combined the teachings of Ohno et al on immediate-release formulations with the teachings of Geyer et al on the rapid disintegrating formulations where the particle size is from 10 to 150 micron with the reasonable expectation of successfully preparing an efficient and fast acting formulation for delivering one or more active agent to patient as quickly as possible.

Claims 4, 7, 11 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geyer et al (5,320,848) in view of McCarty (5,073,374).

Geyer et al, discussed above, lacks specific disclosure on the dissolution time for the immediate-release formulations.

McCarty teach a fast dissolving buccal tablet for administering a medicament includes the active ingredient, a lubricant and a water soluble sugar, such as sorbitol, combined such that the buccal tablet dissolves in about one minute (see abstract). Examples of such medicaments include: steroids such as **estrogens, estradiol**, progestins, propranolol, thyroid hormones, ergotamine, bromocriptine, scopolamine, etc. Buccal administration of estradiol gives an unexpected early peak in the blood level followed by a slowly decreasing concentration. Buccal formulations utilize a disintegrant to accelerate buccal tablet disintegration. Such disintegrants include polyvinylpyrrolidone, starch, alginic acid, sodium starch glycolate, etc (col. 1, lines 23-56).

McCarty teaches that the soluble excipient is typically a sugar, such as sucrose, lactose or sorbitol. The suitable surfactants include sodium lauryl sulfate, polyethylene glycol, magnesium stearate, sodium dodecyl sulfate, etc.

McCarty discloses that the formulations can be prepared by simply mixing the ingredients. The formulation, upon administration, is said to disintegrate in about **30 seconds** to around 5 minutes (col. 2, lines 45-53).

It is then shown that Geyer et al discloses a chewable drug delivery system comprising a drug, surfactants and a rapid dispersal agent with particle size of less than 150 micron. McCarty teaches fast dissolving formulations

comprising active agents, surfactants, wetting agents and lubricants which dissolve in less than 1 minute and preferably in about 30 seconds. Thus It would have been obvious to one of ordinary skill in the art to have combined the two references and prepared a immediate-release formulation which provides a fast acting medicaments for patients who need such therapies. In other words one of ordinary skill in the art has been enabled to make and use the invention as claimed.

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geyer et al (5,320,848) in view of Mundt (6,978,894).

Geyer et al, discussed above, lacks specific disclosure on packaging of the pharmaceutical formulations.

Mundt teaches a blister package for pharmaceutical treatment card comprising a plurality of individual blisters suitable for containing pre-measured dosage of a pharmaceutical composition in the form of tablets, pills and capsules. Accordingly each blister is sealed and may be opened by a method of tearing, peeling or pushing (see abstract). The said blister package may comprise a peelable, backing layer abutting the lidding layer opposite the blister layer, or other blister formats, wherein an individual blister cavity being opened by a method of tearing away a portion of the barrier strip to expose a portion of a

notch cavity, peeling said backing layer away from the lidding layer (see col. 2, line 25 to col. 3, line 31).

It would have been obvious to one of ordinary skill in the art to have looked at the suitable packaging system taught by Mundt to package the dosage form disclosed by Geyer et al because of the need for safety, accessibility and reliability in getting a pharmaceutical dosage form from manufacturer to the ultimate user.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian
Patent Examiner
Art Unit 1616
December 19, 2006